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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,169	06/14/2005	Frank Brady	PZ02108	9282

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,169	BRADY ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 4 and 15 are pending in the application. Claim 5 was canceled and claim 15 newly added in the amendment filed 5/1410. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

New Grounds of Rejection/Objection Necessitated by the Amendment

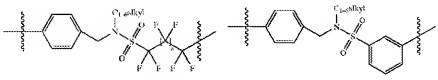
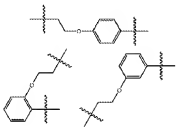
Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luthra et al. (US 2004/0236085) in view of Stevens et al. (WO01/14354) and Scheler (US 4,540,648).

3. Luthra et al. (US 2004/0236085) discloses a solid-phase process for the production of ^{18}F-radiolabelled tracers which are suitable for use as Positron Emission Tomography (PET) radiotracers (abstract; p1, [0001]; p6, [0099]). The process for the production of radiolabelled tracers comprise a.) treatment of a resin-bound precursor, SOLID SUPPORT-LINKER-I^{+}-TRACER Y^{-}, with ^{18}F^{-} to produce the labeled tracer, ^{18}F-TRACER; b.) removal of excess ^{18}F^{-} by ion-exchange chromatography; c.) removal of any protecting groups; d.) removal of organic solvent; e.) formulation of the resultant ^{18}F-TRACER as an aqueous solution (p1, [0004-0006], [0008-0015]; p5, [0070-0076]).

The solid support may comprise polystyrene and the linker may comprise zero to four aryl groups (suitably phenyl) and/or a C_{1-6} alkyl and optionally one to four additional functional groups (not excluding alkoxy),  , etc. and may further comprise an aryl group (suitably phenyl) adjacent to the I^+. Preferred examples include  (p1, [0018-0019]; p5, [0079]). The SUPPORT-LINKER of the disclosure encompasses the SUPPORT-LINKER of the instant claims and Y^- (i.e. triflate) encompasses the Y^- (anion) of the instant claims. The solid-phase process provides for producing ^{18}F-labelled tracers used for PET quickly and with high specific activity yet avoiding time-consuming purification steps. The solid-phase methods also lend themselves to automation with advantages of ease of production and greater throughput (p1, [0003]). Luthra et al. does not disclose a benzothiazole TRACER.

4. Stevens et al. (WO01/14354) discloses ^{18}F-substituted benzothiazoles for use in PET (p5, lines 3-17).

5. Scheler (US 4,540,648) discloses a benzothiazole/light sensitive compound linked to a solid support/film (i.e. polystyrene) via a coupler component (abstract; column 3, lines 25+; column 7, lines 5-11 and 60-66; claim 1). The polystyrene solid

support encompasses the solid support of the disclosure as evidenced in the specification p6, lines 1-8.

6. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the benzothiazole/light sensitive compound of Stevens et al. and Scheler for the TRACER of Luthra et al. to generate a ^{18}F radiolabelled benzothiazole (derivative) via the polymer-bound/solid support of Luthra et al. as Stevens et al. teaches that ^{18}F-substituted benzothiazoles were known at the time of the invention. Also, it would have been obvious to one ordinarily skilled in the art to attach a benzothiazole (derivative) to the polystyrene solid support (Luthra et al.) as Scheler also teaches that benzothiazole may be linked to a polystyrene solid support via a coupler.

7. Luthra et al. and Stevens both teach of ^{18}F radiolabelled radiopharmaceutical agents for use in PET. It would have been predictable and advantageous to use the polymer-bound/solid support of Luthra et al. to radiolabel benzothiazoles with ^{18}F to avoid time consuming purification steps and allow for ease of production and greater throughput (Luthra et al.; p1, [0003], [0006]; p6, [0099]).

Response to Arguments

8. Applicant's arguments filed 5/14/10 have been fully considered but they are not persuasive.

9. Applicant asserts that Luthra et al. fails to teach or suggest the labeling of benzothiazole compounds, much less the regiospecific labeling of benzothiazole

compounds. Hence Luthra et al. fails to teach or suggest Applicant's claimed regiospecific benzothiazole 18F-labeling process.

10. The reference of Luthra et al. was not used to teach of benzothiazole tracers but was used to teach of the general solid-phase process for the production of ^{18}F-radiolabelled tracers which are suitable for use as Positron Emission Tomography (PET) radiotracers. The solid-phase process provides for producing ^{18}F-labelled tracers used for PET quickly and with high specific activity yet avoiding time-consuming purification steps. The solid-phase methods also lend themselves to automation with advantages of ease of production and greater throughput. The method steps of the solid-phase process encompasses the method steps of the process of the instant claims.

11. Scheler teaches that benzothiazole may be linked to a polystyrene solid support via a coupler.

12. Stevens et al. teaches of ^{18}F-substituted benzothiazoles were known in the art and used as PET tracers at the time of the invention.

13. Therefore, it would have been obvious to one ordinarily skilled in the art to attach a benzothiazole (derivative) to the polystyrene solid support such as that of Luthra et al. to avoid time consuming purification steps and allow for ease of production and greater throughput of a ^{18}F-substituted benzothiazoles, such as that of Stevens et al. for use in PET.

14. Applicant asserts that Stevens et al. describes that their 18F labeled compounds are prepared from the corresponding iodo substituted compound and is silent as to Applicant's claimed process.

15. The reference of Stevens et al. was not used to teach of the method of preparing the ^{18}F-substituted benzothiazoles but was used to teach that ^{18}F-substituted benzothiazoles were known in the art at the time of the invention and used as PET radiotracers.

16. The reference of Luthra et al. was used to teach of the general solid-phase process for the production of ^{18}F-radiolabelled tracers which are suitable for use as Positron Emission Tomography (PET) radiotracers. The solid-phase process provides for producing ^{18}F-labelled tracers used for PET quickly and with high specific activity yet avoiding time-consuming purification steps. The solid-phase methods also lend themselves to automation with advantages of ease of production and greater throughput.

17. Scheler teaches that benzothiazole may be linked to a polystyrene solid support via a coupler.

18. Therefore, it would have been obvious to one ordinarily skilled in the art to attach a benzothiazole (derivative) to the polystyrene solid support such as that of Luthra et al. to avoid time consuming purification steps and allow for ease of production and greater throughput of a ^{18}F-substituted benzothiazoles, such as that of Stevens et al. for use in PET.

19. Applicant asserts that Scheler is wholly unconcerned with radiofluorination of benzothiazole compounds. Thus one of skill in the art would not be motivated by either Stevens or Scheler to regiospecifically radiofluorinate a benzothiazole compound according to Applicant's claimed process.

20. The reference of Scheler was not used to teach of radiofluorination of benzothiazole compounds but was used to teach that benzothiazole may be linked to a polystyrene solid support via a coupler and thus it was known in the art at the time of the invention to link a benzothiazole to a polystyrene solid support.

21. The reference of Stevens et al. was not used to teach of the method of radiofluorination of benzothiazole compounds but was used to teach that ^{18}F-substituted benzothiazoles were known in the art at the time of the invention and used as PET radiotracers.

22. The reference of Luthra et al. was used to teach of the general solid-phase process for the production of ^{18}F-radiolabelled tracers which are suitable for use as Positron Emission Tomography (PET) radiotracers. The solid-phase process provides for producing ^{18}F-labelled tracers used for PET quickly and with high specific activity yet avoiding time-consuming purification steps. The solid-phase methods also lend themselves to automation with advantages of ease of production and greater throughput.

23. Therefore, it would have been obvious to one ordinarily skilled in the art to attach a benzothiazole (derivative) to the polystyrene solid support such as that of Luthra et al. to avoid time consuming purification steps and allow for ease of production and greater

throughput of a ^{18}F-substituted benzothiazoles, such as that of Stevens et al. for use in PET.

Conclusion

24. No claims are allowed at this time.

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618